

June 7, 2017

California Environmental protection Agency
Office of Environmental Health Hazard Assessment (OEHHA)
P.O.Box 4010, MS-12B
1001 I Street
Sacramento, CA 95812
Attn: Ms. Esther Barajas-Ochoa
Regulations Coordinator

Re. Proposed No Significant Risk Level (NSRL) for the chemical glyphosate to be adopted into regulation in Title 27, California Code of Regulations, Section 25706

Dear members of OEHHA:

I want to thank the CA-EPA, OEHHA, for this opportunity to provide information and/or a new perspective regarding the recently proposed No Significant Risk Level (NSLR) of 1100 µg glyphosate/kg body weight/day. It is my opinion that this level is unacceptable for a number of reasons that are provided herein.

STANDARDS

Developing an NSRL that relies on “acceptable calculated reference doses” supplied by the US EPA and its international counterparts is generally troublesome. That is, the EU “standard” for daily chronic exposure to GLY is 0.5mg/kg body weight, a level that is 3.5 fold *lower* than the U.S. “standard” of 1.75mg/kg body weight [[Benbrook. 2016. Environ Sci Eur 28:3](#)]. Obviously, both levels cannot be *acceptable* and *safe*; and the EU version is already less than half of the proposed 1.1mg by OEHHA.

Such “standards” (e.g., UK Food Standards, EPA Chronic Reference Dose, EU Acceptable Daily Intake) have no rigorous scientific basis, are not supported by meaningful data with real world formulations (including combinations of pesticides that might be applied simultaneously or sequentially [[Corroborated June 14, 2016 by the US EPA, glyphosate meeting hosted by Congressman Ted Lieu, Washington, DC,](#)]; are not tested on all foods or all age groups; etc. Further, as industrial agriculture applications of glyphosate have expanded, so has the contamination increased in food and water. In response, US authorities periodically elevate the maximum allowable “safe” amount of glyphosate residue in what we eat and drink. Such adjustments, while based on quantification of crop residues by laboratory analysis, are actually pragmatic decisions to accommodate existing real world residue levels of existing agricultural practices [[Cuha, et. al. 2016. Front Envir Sci 28](#)]. Essentially, current “standards” are arbitrary levels established largely by industry from data that is often not peer reviewed. This is not reliable science and does not follow the precautionary principle.

TOXICITY

Glyphosate’s effects are not dose dependent; it does not have a linear “dose makes the poison” (monotonic) pattern of toxicity. NSLR’s are focused on the monotonic principle where the more poison the greater the adverse effect. Glyphosate does not fit the

common pattern of “acute” and “chronic” toxicity. As is known for endocrine disrupting compounds, glyphosate has a non-monotonic (non-linear) response that damages life at very low concentrations, including cancer.

[Vandenberg, et.al. 2012. Endocr Rev 33; Thongprakaisang, et. al. 2013. Food Chem Toxicol 39; Samsel & Seneff. 2013. Entropy 15]

BIOACCUMULATION

Using radiolabelled glyphosate, Monsanto found that about 30% of ingested glyphosate is retained in animals (the rest is excreted in urine & feces), and of that, about 1%+ glyphosate bioaccumulates in virtually all tissues (blood, bone, bone marrow, glands, organs, etc.), with an affinity for bone and for male subjects.

[Ridley and Mirley. 1988. Unpubl. study MSL-7215 submitted to the EPA - MRID#407671-01; Samsel & Seneff. 2015. J Biol Phys Chem 15]

PHARMACOKINETICS

Glyphosate [*N*-(phosphonomethyl) glycine] is a synthetic amino acid that is structurally similar to glycine, one of our most abundant amino acids.

Sidebar - GLYCINE 101: There are 20 amino acids that are the building blocks of biology, vital for our body to function and synthesize proteins. All life forms basically share some combination of these same amino acids with specific functions. Glycine is our smallest amino acid, the simplest in structure, and the second most widespread amino acid found in human enzymes and proteins. Glycine is important to us, including:

- for the construction of healthy DNA and RNA strands, the genetic building blocks that are necessary for the proper function of our body's cells (structure & function)
- as one of the two (with arginine) amino acids that form creatine, which can help to promote muscle growth and energy production during exercise, and one of three amino acids in glutathione, an important antioxidant
- it is the primary component of collagen, the non-contractile connective tissue that makes up most of your skin, tendons, and ligaments; it gives us our curves and facial features
- it helps the body regulate blood sugar levels and provide glucose to various body tissues for energy
- the digestive system relies on glycine in order to function normally
- a major supplier of methyl groups that regulate gene expression
- it affects the production of brain neurotransmitters, which are essential for maintaining normal brain function and emotions

To understand glyphosate's unique toxicity, let's follow what happens in an exposure:

A glyphosate exposure occurs: ingested from contaminated food/drink, absorbed through skin, inhaled, or injected in a vaccine. Every new exposure provides another dose of glyphosate in the body.

Glyphosate goes to the stomach & intestines to end up in the bloodstream (more directly and rapidly for vaccine-sourced glyphosate).

Glyphosate constantly circulates in the bloodstream — the beta half-life is 7-14 days; it also circulates in the lymphatic system and in cerebrospinal fluid. Glyphosate goes wherever the amino acid glycine would go, to all tissues. Monsanto found it in blood cells, bone, bone marrow, brain (it penetrates the blood/brain barrier).

Glyphosate goes from the capillaries into the extracellular matrix (ECM) that surrounds every cell throughout the body.

Sidebar - Extra Cellular Matrix 101: The ECM is the collection of extracellular molecules (fibrous proteins, much of it collagens, and glycosaminoglycans) secreted by cells that provides structural and biochemical support to the surrounding cells. The extracellular matrix regulates a cell's dynamic behavior; it manages mitochondria within the cell. Due to its diverse nature and composition, the ECM can serve many functions, such as providing support, segregating tissues from one another, and regulating intercellular communication. Importantly, the ECM provides structural firmness (via collagens) and elasticity and flexibility (via a different protein, elastin) for our tissues and organs. Collagens make up about 25%+ of the total amount of proteins in the body and may be thought of as the glue that holds the body together.

Some glyphosate molecules attach to the sugar polymer structure of the ECM and can be released; however, about 1%+ cross the cell wall molecule-by-molecule. Within the cell, randomly, RNA can mistakenly use glyphosate in place of glycine for protein synthesis; that is, it misincorporates glyphosate into peptides and proteins that are now malformed (i.e., misfolded) and will no longer function as originally intended in metabolism and other regulatory processes. [[Samsel & Seneff. 2016 & 2017. J Biol Phys Chem 16 & 17](#)]

The malformed proteins are then secreted back into the ECM as collagens and other proteins. Now, throughout the body, there are defective proteins in the ECM that participate in cell management, communication, tissue structure, etc. For example, collagen will be utilized in bone, skin, muscle, tendons, cartilage, teeth, corneas, or whatever needs collagen, but the integrity and functionality of that collagen is now defective. Or consider other proteins such as defective digestive enzymes that can no longer function in breaking down food into nutrients that can be absorbed by our bodies. This negatively affects our biology at a very fundamental level.

Glyphosate has now been isolated in collagens and enzymes. The only way it can get there is via misincorporation during protein synthesis within a cell, or has been bound to a protein, and has been secreted back out into the ECM. In essence, this demonstrates how glyphosate misincorporates into proteins and, basically, how it bioaccumulates. [[Samsel & Seneff. 2017. J Biol Phys Chem 17](#)]; [Xu, et.al. 2016. Chemosphere 145](#)]

HOW MUCH GLYPHOSATE & DIS-EASE

Note that glyphosate (technical acid) at a concentration of 1ppb (1µg/L) contains 3.561 trillion molecules of glyphosate in one liter of water. A single MMR vaccination (@ 3.74 ppb, and depending on volume) could put millions of molecules of glyphosate into a child at one sitting. The OEHHA proposal of 1100 ppb could allow trillions to

quadrillions of molecules of glyphosate per daily intake. Remember, glyphosate circulates in our bodies for up to two weeks, it misincorporates into proteins, and it bioaccumulates in all tissues, organs, & bodily fluids. How many different exposures are likely to occur in a day, week or month? How large is each exposure? What is the frequency of such exposures? How could one possibly regulate intake with any degree of accuracy?

Each circulating glyphosate molecule is capable of changing a protein's structure at the cellular level. This disrupts the proteins' functions (i.e., harms all life) at a fundamental level and the consequences are unpredictable. Medical chaos results, with a constant, insidious onset of dysfunction and dis-ease of many types, including cancer & cancer-linked conditions, for example:

- disruption of the gut microbiome that favors pathogenic microbes leading to chronic inflammation in the gut
- impaired gut barrier; thin, porous gut lining
- functional disruption of enzymes and other proteins
- oxidative stress
- metabolic disorders
- DNA damage

It is virtually impossible to protect oneself from this all-pervasive chemical.

[Eriksson, et.al. 2008. *Int J Cancer* 123; Guitheme, et.al. 2012. *Ecotoxicology* 21; IARC. 2015. *IARC Monographs V.112*; King, et.al. 2006. *Oncogene* 25; Lankas & Hogan. 1982. *Unpubl. Monsanto Proj. #77-2062* rec'd by EPA 20Jan.1982 under 524-308; Marc, et.al. 2004. *Biol Cell* 96; Samsel & Seneff. 2015 & 2017. *J Biol Phys Chem* 15 & 17; Séralini, et. al. 2014. *Environ Sci Eur* 26; Shehata, et. al. 2013. *Curr Microbiol* 66; Thongprakaisang, et.al. 2013. *Food Chem Toxicol* 39]

ADMINISTRATIVE & RELATED SCIENTIFIC PROBLEMS

The cancer-related data that has been provided over the years by the EPA has recently been brought into question because of apparent collusion between Monsanto and certain individuals at the EPA, all for the benefit of Monsanto.

[Pollack. *NYT*. Mar. 27, 2015; Hakim. *NYT*. Mar.14, 2017; McPhate. *NYT*. Apr.10, 2017]

Because of this apparent collusion, U.S. Congressman Ted Lieu recently issued a Press Release stating that “consumers should immediately stop using Roundup” because of the Non-Hodgkin lymphoma risk as determined by the WHO International Agency for Research on Cancer (IARC).

[Rep. Lieu Statement on New Glyphosate Safety Concerns. Press Release, Mar. 15, 2017; IARC. 2015. *IARC Monographs V.112*]

Rep. Lieu's Press Release also stated “a Department of Justice investigation is warranted to look at any potential misconduct by employees at the EPA”. **A week ago, the EPA's Inspector General (part of the DOJ) requested the EPA OIG Office of Investigations “to conduct an inquiry into several agency glyphosate review-related matters”.**

[Letter, May 31,2017, from A.A.Elkins, Jr., IG, EPA, OIG to Congressman Ted Lieu]

The entire relationship between Monsanto and the EPA appears to have been corrupt for many years. Therefore, the glyphosate regulatory decisions of the EPA over those years are certainly questionable, including, the original registration of glyphosate and the on-going re-registration process. Until the tainted administrative and scientific issues are properly sorted out, glyphosate should not be allowed on the market at any concentration because the potential risks are, *and have been*, far too great.

Overall, glyphosate poses an unreasonable risk of adverse effects to humans, animals and the environment. There is no "safe level" for glyphosate and it *should not be* in our food supply, water, air, soil or vaccines — it causes damage wherever it goes.

Thank you for your kind consideration of my comments on the proposed NSRL for glyphosate, I look forward to your final regulatory decision.

Sincerely,

A handwritten signature in black ink, appearing to read 'Stephen C. Frantz', with a long horizontal line extending to the right.

Dr. Stephen C. Frantz
Principal
Global Environmental Options
23047 Mulholland Drive
Woodland Hills, CA 91364

TED W. LIEU
33RD DISTRICT, CALIFORNIA

COMMITTEE ON THE
JUDICIARY

COMMITTEE ON
FOREIGN AFFAIRS

Congress of the United States
House of Representatives
Washington, DC 20515-0533

236 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-3976

5055 WILSHIRE BOULEVARD, SUITE 310
LOS ANGELES, CA 90036
(310) 652-3095

1600 ROSECRANS AVENUE, 4TH FLOOR
MANHATTAN BEACH, CA 90266
(310) 321-7664

May 19, 2017

Mr. Arthur Elkins, Jr.
Inspector General
Environmental Protection Agency
Office of Inspector General
1200 Pennsylvania Avenue, N.W. (2410T)
Washington, DC 20460

Dear Mr. Elkins:

Thank you for your public service. I have deep concerns with the Environmental Protection Agency's registration review of the pesticide glyphosate, a potentially harmful chemical to humans. California recently declared glyphosate a carcinogen. Monsanto manufactures Roundup, which has glyphosate as its active ingredient. There are reports that an EPA employee may have colluded with Monsanto to conduct a biased review of glyphosate. I respectfully request that you conduct an investigation into whether there was misconduct between the EPA and Monsanto related to EPA's review of glyphosate.

Judge Vince Chhabria of the Northern District of California is presently hearing a case related to the liability of Monsanto regarding Roundup. On March 13, 2017, Judge Chhabria denied Monsanto's request to seal documents related to the EPA's review of glyphosate and the work of EPA official Jess Rowland. According to a subsequent *New York Times* article, the unsealed documents revealed that Monsanto was responsible for ghostwriting academic research on glyphosate. Further, they showed that Rowland had assured Monsanto that the Department of Health and Human Services would not conduct a pesticide review of glyphosate.

If these accounts are true, I believe they raise serious concerns about the legitimacy of the glyphosate registration review. As such, I urge you to conduct an investigation. Some questions that need to be addressed include the following:

- Are there any communications between EPA officials and Monsanto that show any potential wrongdoing on the part of EPA or Monsanto employees?
- Is there any evidence that EPA's registration review of glyphosate was biased, unfair, or lacking in scientific rigor?
- Did an EPA official state or suggest that EPA would prevent any review of glyphosate by the Department of Health and Human Services?

- What efforts, if any, are being taken to ensure the integrity of EPA's current glyphosate registration review?
- What is the current status of the EPA's glyphosate registration review?

Thank you for your time and consideration.

Sincerely,



Ted W. Lieu
Member of Congress



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

MAY 31 2017

The Honorable Ted W. Lieu
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Lieu:

Thank you for your May 19, 2017, letter to the U.S. Environmental Protection Agency (EPA's) Office of Inspector General (OIG) requesting an investigation into reports that an EPA employee may have colluded with Monsanto to conduct a biased review of glyphosate.

As you are aware, there is considerable public interest regarding allegations of such collusion. As a result, I have asked the EPA OIG Office of Investigations to conduct an inquiry into several agency glyphosate review-related matters. Your letter has been forwarded to the EPA OIG Office of Investigations for inclusion and consideration.

Following the completion of the review, we will notify your staff and prepare the appropriate response to your concerns.

We appreciate your interest in the work of the EPA OIG. If you have any questions regarding this or any other matter, please contact Alan Larsen, Counsel to the Inspector General, at (202) 566-2391.

Sincerely,



Arthur A. Elkins Jr.